इंटरनेट मानक

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Mazdoor Kisan Shakti Sangathan
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Jawaharlal Nehru
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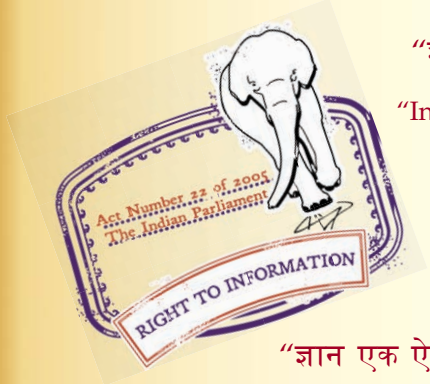
IS 3387 (2004): Toothbrush [CHD 24: Brushware]



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"ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है"
Bhartṛhari—Nītiśatakam
"Knowledge is such a treasure which cannot be stolen"

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भारतीय मानक

टुथब्रश — विशिष्टि

(दूसरा पुनरीक्षण)

Indian Standard

TOOTHBRUSH — SPECIFICATION

(Second Revision)

ICS 97.170

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

August 2004

Price Group 4

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Brushware Sectional Committee had been approved by the Chemical Division Council.

A good toothbrush should provide not only efficient cleaning of the tooth surfaces but massaging of the gums to some extent. A toothbrush may render both these functions if it is properly shaped and designed. Common teeth and gum troubles may be due either to inadequate oral hygiene or may be result of sub-standard quality of toothbrush.

The standard was originally published in 1965. In the original standard toothbrushes were permitted to fill with either bristles or nylon monofilaments. Toothbrushes filled with bristles cause less tooth abrasion, tooth neck defects and gingival injuries. Both types of brushes show an insignificant difference in bacterial culture after brushing. Since the production of toothbrushes filled with bristles is meagre, first revision was taken up in 1973 to cover only toothbrushes filled with nylon monofilaments.

Due to lack of unanimity of dental profession regarding the ideal trim conducive to the satisfactory ultimate performance of the toothbrush, the type of the trim has not been specified. But it was agreed that this aspect should be specified in a more objective manner as and when more data is available.

With the experience of about last three decade and technical development in this area, the Committee decided to revise the standard for its updation and to bring it in line with other international standard. In this revision the scope of materials used in cleaning elements and handle's material are widened based on the development with the aim of betterment of the product. During this revision, instrumental method for quantifying pull strength for tuft and end rounding of tips of filaments are incorporated, requirements of number of filaments have been simplified and rationalized to give the opportunity to creative design.

There is no ISO standard on this subject. The standard has been prepared based on the indigenous technology available in the country and assistance has been taken from JIS S 3016-1985 'Toothbrushes'.

The composition of the Committee responsible for formulation of this standard is given in Annex D.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

TOOTHBRUSH — SPECIFICATION

(Second Revision)

1 SCOPE

This standard prescribes the materials, methods of sampling and tests for toothbrushes manufactured for oral hygiene.

2 REFERENCES

The standards listed below contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreement based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.	*Title*
1843 : 1963	Nylon monofilaments
2267 : 1995	Polystyrene moulding and extrusion materials — Specification
10951 : 1984	Polypropylene materials for moulding and extrusion (*first revision*)
13193 : 1992	Polyal kylene terephthalates (PET and PBT) for moulding and extrusion
14434 : 1998	Polycarbonate moulding and extrison material — Specification
14753 : 1999	Polymethyl methacrylate (PMMA) (acrylic) sheets

3 TERMINOLOGY

For the purpose of this standard, the following definitions shall apply:

3.1 Toothbrush — An implement comprising of the body and a head, designed to help in oral hygiene.

3.2 Head of Toothbrush — The part of toothbrush where cleaning elements are fastened.

3.3 Brush Handle — The entire body of the brush including the head (*see* Fig. 1).

3.4 Cleaning Elements — The protrusions fixed on the brush head, which is designed to impart the cleaning of the tooth surface, interproximal spaces and near gum line. It may consist of filaments, tufts made of filaments or specially designed elements (for example lamella) of synthetic materials.

3.5 Tuft — In case the cleaning element consists of filaments, the tuft is a bunch of filaments in each hole in the head of toothbrush.

3.6 Trim Height — Total protrusion of cleaning element from surface of the head of brush.

3.7 End Rounding — The shape of the tips of the cleaning filament.

3.8 Pull Strength — The force required to pull out a cleaning element from head of toothbrush.

3.9 Anchor Wire — In case filaments are used in a cleaning element in a staple technology, the anchor wire is the wire which is used to fix a bunch of filaments (that is a tuft) in to the hole in head of toothbrush.

4 SIZES AND TYPES

4.1 Sizes

Toothbrushes shall be of the following sizes

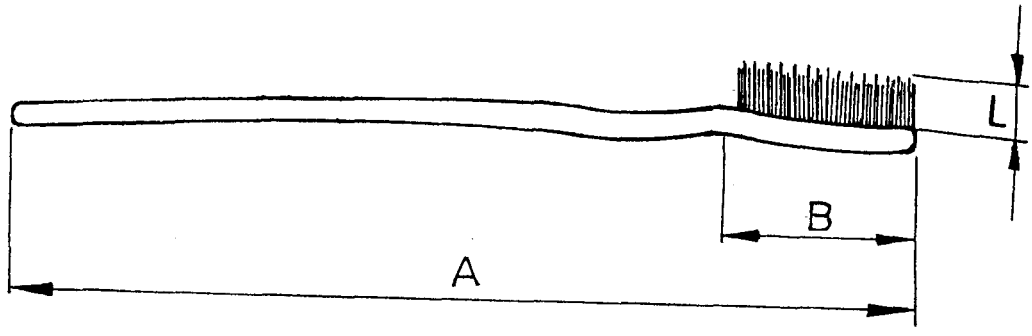

FIG. 1 BRUSH HANDLE WITH BRUSH HEAD

depending on the length of handle:

Variant	*Minimum Length of Handle* mm
Adult	150
Junior	120
Baby	90

4.1.1 Toothbrush may or may not have the gum stimulator. The gum stimulator, if present, shall be made of high density polyethylene or thermo plastic elastomer or any such suitable flexible material. It shall have a smooth small rounded tip. The top portion of gum stimulator shall be flexible and of medium hardness. It shall be attached firmly, preferably at the tail end of toothbrush handle.

4.2 Types

Adult size of the toothbrush shall be of the following types depending upon the gauge of the filaments:

a) Super-soft,
b) Soft,
c) Medium,and
d) Hard.

5 REQUIREMENTS

5.1 Materials

5.1.1 *Cleaning Element*

5.1.1.1 Cleaning element shall consist of nylon filaments — 6, 6; 6, 10; 6, 12, polyester filaments, poly butylene terphthalate filaments, thermoplastic elastomer, polyethylene filaments, polypropylene filaments, or any combinations of above materials and shall be free from any disagreeable odour, taste and toxic elements.

5.1.1.2 Cleaning elements may contain non-toxic colours.

5.1.2 *Filament*

5.1.2.1 The filaments shall be in the form of monofilaments, co-extruded filaments, hollow filaments, filled filaments, or structured filaments.

5.1.2.2 The cross-section of the filaments shall be of circular, square, hexagonal, diamond, rectangular, or any other suitable shape.

5.1.2.3 The diameter of filaments used as filling material in a cleaning element in toothbrushes, shall be as given in Table 1. Tolerance limit for individual filament is ± 0.02 mm of claimed diameter and average of fifty filaments shall fall in the range specified in Table 1.

Table 1 Diameter of Filaments

(*Clause* 5.1.2.3)

Sl No.	Size	Type	Diameter of Filaments *mm*	No. of Mono-filaments, *Min*
(1)	(2)	(3)	(4)	(5)
i)	Adult	Super-soft	0.12 ≤ 0.15	300
ii)	Adult	Soft	> 0.15 ≤ 0.20	300
iii)	Adult	Medium	> 0.20 ≤ 0.25	300
iv)	Adult	Hard	> 0.25 ≤ 0.35	300
v)	Junior	Soft	0.15 – 0.20	250
vi)	Baby	Soft	0.12 – 0.18	250

5.1.3 *Handle*

It shall be manufactured from the following plastic materials and shall be free from disagreeable odour and test :

a) Polystyrene moulding powder (*see* IS 2267),
b) Polypropylene moulding powder (Homopolymer, co-polymer) (*see* IS 10951),
c) Cellulose acetate propionate moulding powder,
d) Styrene acrylonitrile (SAN),
e) Polyethylene terphthalate (*see* IS 13193),
f) Polycarbonate (*see* IS 14434),
g) Acrylonitrile butadiene styrene (ABS),
h) Methacrylate butadiene styrene (MBS),
j) Poly methyl methacrylate (*see* IS 14753), and
k) Thermoplastic elastomer (TPE).

The manufacturer may choose to design his brush handle from one or more polymers from above list.

5.1.4 *Anchor Wire*

Anchor wire is generally used for toothbrush manufactured by tufting/staple technology. It shall consist of aluminium, brass, nickel-silver, or any other suitable non-corrosive materials.

5.2 Manufacture

5.2.1 The manufacturer shall choose to design the cleaning elements in toothbrush head through combinations given in **5.1.1**.

NOTE — Presently there are several designs of toothbrushes of different sizes in the market having a wide variation as regards to number of tufts per brush, hole diameter and hence number of filaments

per tuft. Moreover, toothbrushes based on novel cleaning elements (such as lamella) made from novel materials have entered international and local markets. It is, therefore, not practical to lay down specifications in these respect with a view to accommodating all designs.

A good toothbrush should provide both efficient cleaning and gum massage to some extent and all designs should aim to deliver these benefits. The manufacturer has his choice in design of the brush head in terms of cleaning element design, number of tufts per brush, number of filaments per tuft and filaments/cleaning element material to deliver cleaning and gum massaging as long as he conforms to the stipulated guidelines.

5.2.2 *Handle*

The handles, either transparent or opaque, may be manufactured in various colours and shades. The width and thickness of the handle may vary according to individual design, but the head shall be designed to allow for fixing of the cleaning element so as to meet the stipulated pull strength requirement. The head shall not have any protruding parts.

5.2.3 *Pigments for Handle Colours*

Only food wrapper grade pigments certified with analytical details by pigment manufacturer should be used for colouration of handles.

5.2.4 Head shape may be either rectangular, diamond, oval, round or any other shape to suit individual design.

5.2.5 The maximum width of head of the toothbrush shall not be more than 13 mm for rectangular head, 15.5 mm for diamond, round, oval and other shape in case of adult; 12 mm in case of junior and 9 mm in case of baby size.

5.2.6 The portion of the handle used for holding may have elastomers such as TPE, rubber, combination of rubber and other molding material or materials mentioned in **4.2** for better grip and/or aesthetics.

5.2.7 The head and/or neck portion may have thermoplastic elastomer (TPE) for flexibility.

5.2.8 The tail portion of the handle may or may not have a hole circular or otherwise, to facilitate hygienic storage.

5.3 Tufting

5.3.1 Cleaning element should be fixed to brush head using a suitable technology such as staple technology using an anchor wire, welding technology, fusion technology, inmold welding technology etc.

5.3.2 In case of toothbrushes in which anchor wire is used for fixing each cleaning element which is in the form of a tuft, it shall be individually fixed in a suitable sized tuft hole on the brush head and sunk to the depth up to start of bottom cup of the hole (*see* Fig. 2).

5.3.3 The maximum protrusion of the cleaning elements from surface of head shall be 13 mm.

NOTE — Stiffness of cleaning material mainly depends on the material used, cross-sectional area and length. In case the filaments are used in the cleaning element, the stiffness of a tuft is mainly dependent on diameter of filament as well as trim height. According to up to date findings of the dental profession the optimum protrusion of the filling material shall be between 10 to 12. Longer lengths have the disadvantage of scattering and bending out early, while protrusion of less than 7 mm is considered not desirable as per JIS S 3016-1985.

5.3.4 The tops of tufts may be trimmed to any profile to suit individual design but shall be in a manner, which does not injure the gums while brushing.

5.4 End Rounding

The heads of monofilaments shall be polished to give them round shape. The end rounding shall not be less than 50 percent when determined according to the method given in Annex A.

5.5 Pull Strength

The force required for pulling out an individual tuft shall not be less than 1.0 kg when tested according to the method given in Annex B.

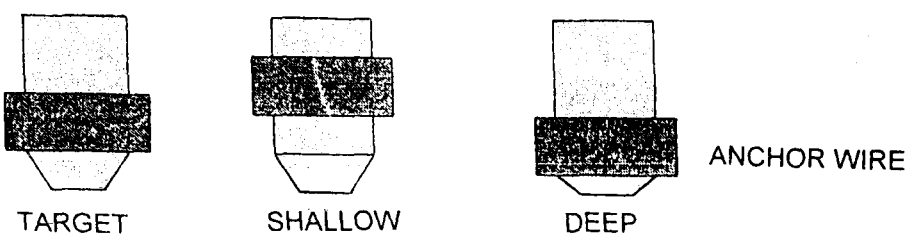

FIG. 2 USE OF ANCHOR WIRE IN TUFTING

6 MARKING

6.1 Unless otherwise agreed to between the purchaser and the supplier, each brush shall be legibly and indelibly marked or stamped with manufacturer's name or recognized trade-mark, if any, and the type of brush.

6.1.1 *BIS Certification Marking*

Toothbrushes may also be marked with the Standard Mark.

6.1.1.1 The use of the Standard Mark is governed by the provisions of *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

7 PACKING

7.1 The toothbrushes shall be packed individually in suitable containers to protect them hygienically from external elements.

NOTE — Typical containers are paperboard or PVC blister or combination of PVC-PVC/ PVC-paperboard combination, polyethylene pouch, Plastic containers, BOPP or any other suitable container.

7.2 These individually packed brushes shall be packed further as per mutual agreement between the purchaser and the supplier to facilitate transport, storage and display.

8 SAMPLING

Representative samples for test shall be drawn as prescribed in Annex C.

ANNEX A

(*Clause* 5.4)

DETERMINATION OF END ROUNDING

A-1 GENERAL

Although this test is subjective in the beginning, one can determine end rounding fairly accurately and results can be reproducible.

A-2 APPARATUS

Simple or compound microscope (advisable) with adequate magnification to observe the end rounding of filament tips

A-3 PROCEDURE

Select three tufts in a toothbrush — middle tuft of second horizontal row from top of toothbrush head and two middle tufts of second horizontal row from bottom of toothbrush head — to ensure maximum area coverage.

A-3.1 Count number of tips of monofilaments in each selected tufts — E_1, E_2, E_3.

where

E_1 = number of tips of monofilaments in first tuff,

E_2 = number of tips of monofilaments in second tuff, and

E_3 = number of tips of monofilaments in third tuff.

A-3.2 Strand Count = E_1 or E_2 or $E_3/2$

A-3.3 Observe the end rounding of the tips of monofilaments from each selected tufts under microscope and count the number of tips with acceptable end rounding. The tips of monofilaments with any sort of sharp angles/corners or edges shall be unacceptable and those without any such sharp angles/corners or edges shall be acceptable (*see* Fig. 2). Note down the findings — OK_1, OK_2, OK_3.

where

OK_1 = number of tips of acceptable monofilament in first tuff,

OK_2 = number of tips of acceptable monofilament in second tuff, and

OK_3 = number of tips of acceptable monofilament in third tuff.

A-3.4 Calculation

$$\text{End-rounding, percent} = \frac{(OK_1 + OK_2 + OK_3)}{E_1 + E_2 + E_3} \times 100$$

A-3.5 Repeat the same procedure for two more toothbrushes from a lot.

A-3.6 Take average of end-rounding of three toothbrushes.

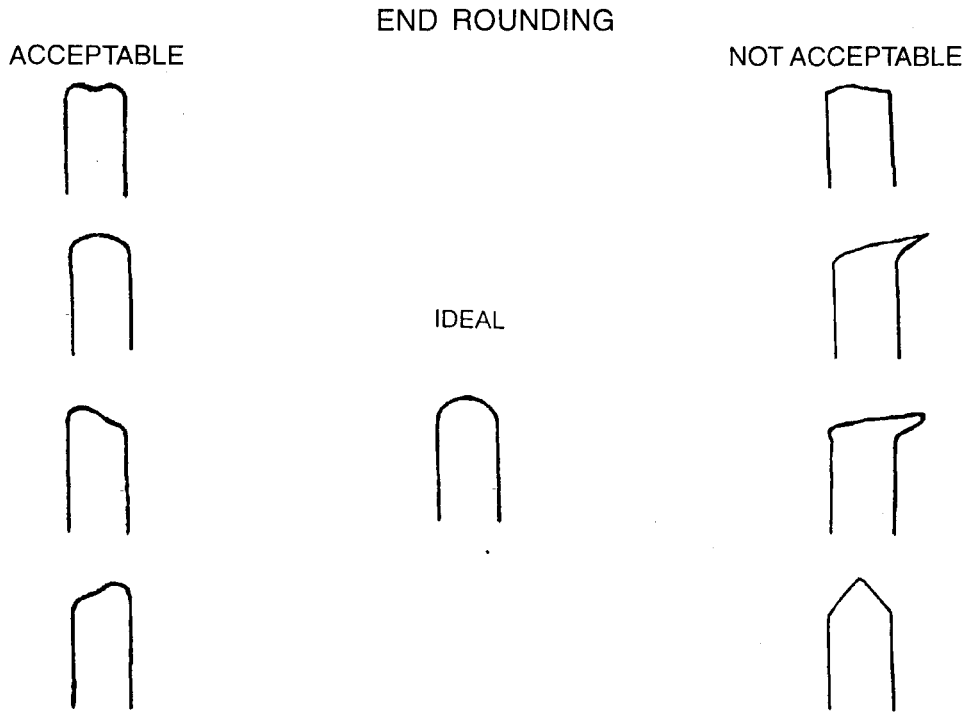

FIG. 3 GUIDELINES FOR ACCEPTABLE AND UNACCEPTABLE END ROUNDING

ANNEX B

(*Clause* 5.5)

DETERMINATION OF PULL STRENGTH

B-1 APPARATUS

A simple instrument as shown in Fig. 4 can be used for testing the pull strength. This unit is suitable for mounting on wall. It consists of dial force gauge/weighing scale operating on spring (*B*) mounted on wooden plate (*A*). A tubular tuft-holder (*C*) is hung on the hook of dial gauge. A clamp for holding toothbrush (*E*) is provided which is movable downward and upward with a screw (*G*).

NOTE — Manufacturer may use sophisticated electronic instrument available in market to determine the pull strength.

B-2 PROCEDURE

B-2.1 Fix a toothbrush head with tufts in upward direction in the toothbrush holder with the help of screw (*F*).

B-2.2 Insert all filaments of one tuft in the hole provided at the bottom of tubular tuft-holder (*C*). Care should be taken not to allow filaments from adjacent tuft to enter in to the hole. Fix the tuft firmly with the help of screw (*D*).

B-2.3 Adjust the pointer on dial to zero by adjustment of screw (*G*).

B-2.4 Move down the toothbrush holder slowly with screw (*G*) watching the pointer on dial carefully. Note down the reading on dial at which the tuft comes out of the hole. This is the pull strength of the tuft.

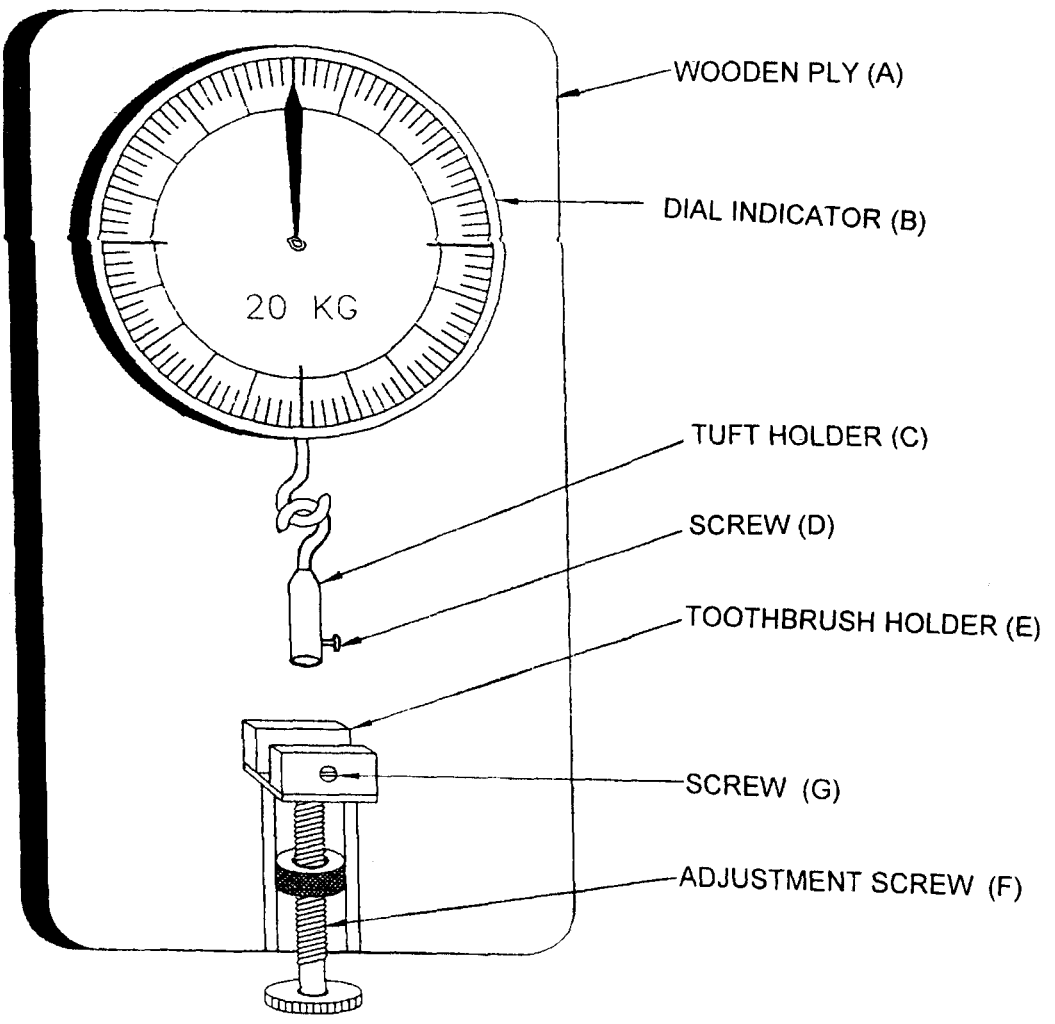

FIG. 4 INSTRUMENT FOR DETERMINATION OF PULL STRENGTH

ANNEX C

(*Clause* 8)

SAMPLING AND CRITERIA FOR CONFORMITY

C-1 SAMPLING

C-1.1 Lot

In any consignment all the toothbrushes of same type, size, design and manufactured from the same materials shall be grouped together to constitute a lot.

C-1.2 The conformity of the toothbrushes in a lot to the requirements of this standard shall ascertained for each lot separately. The number of the toothbrushes to be selected for this purpose shall be in accordance with col 1 and 2 of Table 2.

Table 2 Scale of Sampling

(*Clauses* C-1.2 *and* C-1.3)

Sl No.	No. of Toothbrushes in the Lot	No. of Toothbrushes to be Selected
(1)	(2)	(3)
i)	Up to 50	2
ii)	51 to 100	5
iii)	101 to 200	6
iv)	201 to 300	7
v)	301 to 500	8
vi)	501 and above	9

C-1.3 The toothbrushes shall be selected at random from the top, middle and bottom portion of the package. If the toothbrushes in a lot are packed in more than one package approximately equal number of brushes shall be selected at random from as many packages as possible so as to obtain the required number of toothbrushes for tests, as given in Table 2.

C-2 NUMBER OF TESTS

C-2.1 Test shall be conducted on the individual brushes in the sample.

C-3 CRITERIA FOR CONFORMITY

C-3.1 For declaring the conformity of the lot to the requirements of this standard, all the brushes selected according to **C-1.3** shall satisfy the relevant requirements given in **4** and **5**.

ANNEX D

(*Foreword*)

COMMITTEE COMPOSITION

Brushware Sectional Committee, CHD 24

Organization	*Representative(s)*
A. B. Composite Private Limited, Kolkata	SHRI ANUKUL SAMANTA (***Chairman***) SHRI BASUDEV SAMANTA
All India Plastic Manufacturers' Association, Mumbai	SHRI DINESH KENIA SHRI CHANDRAKANT GOLA (*Alternate*)
A. K. Ghosal and Sons, Kolkata	SHRI R. K. GHOSAL SHRI V. GHOSAL (*Alternate*)
Bharat Heavy Electricals Limited, New Delhi	REPRESENTATIVE
Brushwell and Co, Kolkata	SHRI JAYCHANDRA MEHTA SHRI KETAN SHAH (*Alternate*)
Brush Exports Corporation, Ghaziabad	SHRI MUKESH K. SHARMA SHRIMATI KIRAN KUMARI (*Alternate*)
Central Brush Works, Kolkata	SHRI A. K. SIKDAR SHRI A. SIKDAR (*Alternate*)
Colgate Palmolive (India) Limited, Mumbai	SHRI A. G. GAITONDE SHRI RISHI SRIVASTAVA (*Alternate*)
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Directorate General of Supplies and Disposal, New Delhi	SHRI M. K. UPADHAYA SHRI S. C. CHADHA (*Alternate*)
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BIS Directorate General	SHRI S. K. CHAUDHURI, Director and Head (CHD) [Representing Director General (*Ex-officio*)]

Member Secretary
SHRI N. K. PAL
Director (CHD), BIS

Bureau of Indian Standards

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards : Monthly Additions'.

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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